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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,959	10/30/2003	Hamiduddin Khoja	PP01544.104	8827

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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,959	KHOJA ET AL.	
	Examiner	Art Unit	
	Shulamith H. Shafer, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-4, drawn to a polypeptide, and a composition comprising said polypeptide, classified in class 530, subclass 350.

II. Claim 5, drawn to antibody, classified in class 530, subclass 387.1.

III. Claim(s) 6-13, drawn to polynucleotides, vectors and host cells, classified in class 536, subclass 23.1, 435/320.1 and 435/325.

IV. Claim(s) 14-15, drawn to method of detecting polypeptide utilizing an antibody, classified in class 435, subclass 6.

V. Claim 16, drawn to a method of detecting mRNA by hybridization, classified in class 435, subclass 6.

VI. Claim(s) 17-20, drawn to a method of identifying protein by receptor binding, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these groups constitute patentably distinct inventions for the following reasons. Inventions I-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

The polypeptides of Group I and the polynucleotides of Group III are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid

sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Further, the polypeptides of Invention I can be prepared by processes which are materially different from the nucleic acids of Group III, such as chemical synthesis, or by isolation and purification from natural sources. The nucleic acids of Invention III can be used other than to make the polypeptides of Invention I, such as in gene therapy or a probe in nucleic acid hybridization assays. Furthermore, searching the inventions of Groups I and II together would impose a serious search burden.

The polypeptide of Group I and the antibody of Group II are patentably distinct for the following reasons: while the inventions of both Groups I and II are polypeptides, in this instance, the polypeptide of Group I is a single chain molecule that functions as a receptor, whereas the polypeptide of Group II encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Group I and the antibody of Group II are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group II is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide. Therefore, the polypeptide and antibody are patentably distinct. Furthermore, searching the inventions of Group I and Group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications.

The polynucleotides of Group III and the antibody of Group II are patentably distinct for the following reasons: the antibody of Group II includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of Group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence

open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group III will not encode an antibody of Group II, and an antibody of Group II cannot be encoded by a polynucleotide of Group III. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups II and III would impose a serious search burden since a search of the polynucleotide of Group III would not be used to determine the patentability of an antibody of Group II and vice-versa.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions IV-V are drawn to three different, patentably distinct inventions with different goals, different intermediate steps and different end results.

Invention V is drawn to a method of detecting RNA, whereas Inventions IV and V are directed to methods of identifying or detecting polypeptides. Methods of detecting RNA by hybridization have different goals, different intermediate steps and different end results than do methods of detecting proteins and require different reagents, equipment and protocols than do methods of identifying or detecting polypeptides. The search for the art required for all these inventions would not be co-extensive and would place an undue burden on the examiner and the USPTO resources.

Inventions IV and V are both directed to methods of identifying or detecting polypeptides. However, Invention IV is drawn to a method of detecting polypeptides utilizing an antibody, while Invention VI is drawn to identifying a protein by receptor binding. Each of these Inventions have different goals and different intermediate steps. These methods have a separate status in the art, as evidenced by their different classifications. The search of the art required for these two inventions would not be coextensive.

Inventions I and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention I are not utilized by nor produced by any of the methods of Inventions III-VI. The search of the art for all of these unrelated Inventions would not be co-extensive and would place an undue burden on the examiner and the USPTO resources.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Invention IV can be used in a materially different process than as a method of detecting polypeptides; for example, the antibody can be used to isolate macromolecules from cell homogenates.

Inventions II and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Invention II are not utilized by nor produced by any of the methods of Inventions V-VI. The search of the art for all of these unrelated Inventions would not be co-extensive and would place an undue burden on the examiner and the USPTO resources.

Inventions III and IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Invention III are not utilized by nor produced by any of the methods of Inventions IV and VI. The search of the art for all of

these unrelated Inventions would not be co-extensive and would place an undue burden on the examiner and the USPTO resources.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Invention III can be used in a materially different process than as a method of detecting mRNA; for example, the polynucleotides can be used in gene therapy protocols.

Because these inventions are distinct for reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to the following patentably distinct species of the claimed invention: Sequences.

A. sequence set forth in nucleotides 1-324 of SEQ ID NO:1 and sequence set forth in amino acids 1-80 of SEQ ID:NO 2

B. sequence set forth in nucleotides 652-1890 of SEQ ID NO:1 and sequence set forth in amino acids 189-350 of SEQ ID NO:2
C. SEQ ID NO:1 and SEQ ID NO:2

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph. D. can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

SHS

ELIZABETH KEMMERER
PRIMARY EXAMINER